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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,372	01/25/2002	Kenneth E. Kadziauskas	2783	4335

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,372

Applicant(s)

KADZIAUSKAS ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 - 11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 3/28/02 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the use of legal phraseology throughout, i.e. "said". Correction is required. See MPEP § 608.01(b).
3. The disclosure is objected to because of the following informalities: Page 8, lines 3 states, "indicated arrow 72 as illustrated in Figure 3". There is no arrow referenced by numeral 72 in Figure 3. It appears applicant has mistakenly used reference numeral 72 instead of 71.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to claim 10, it is unclear what is meant by the phrase “enabling the needle lumen through said port” in lines 31 – 32.

Claim 11 recites the limitation "said driver" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Although unclear, the claims have been reviewed by the examiner as best understood at this time in order to continue with the examination.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

Patent No. 6,017,316 to Ritchart et al.

In reference to claims 1, 3, 10 and 11, Ritchart et al. discloses a surgical apparatus as claimed by applicant including: a hollow needle (Col. 5, lines 20 – 21) having a port for enabling tissue entry into the needle lumen (Col. 5, lines 24 – 28); a cutting blade disposed within the hollow needle for severing tissue (Col. 5, line 23); a driver, connected to the cutting blade, for moving the blade between a first and second position, the tissue entering the needle being severed as the blade moves between the first and second position (Col. 6, lines 25 – 62); a vacuum source for causing tissue

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entry into the needle lumen through the port and for aspirating severed tissue (Col. 6, lines 54 – 58); and a controller, including a valve for controlling vacuum communication between the vacuum source and the needle lumen, for coordinating vacuum and blade movement so that vacuum is provided to the needle lumen when the blade is in the first position and during the severing of the tissue by the blade and reducing vacuum to the needle lumen before moving the blade from the second position to the first position. Ritchart et al. discloses stopping the vacuum (Col. 6, line 21 – Col. 8, line 11).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2 and 7 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No. 6,017,316 to Ritchart et al. in view of U.S. Patent No. 5,685,320 to Zimmon et al.

In reference to claims 2 and 7 – 9, Ritchart et al. discloses applying vacuum to the tissue to bring the tissue into the port, and moving the blade to sever tissue (Col. 6, lines 54 – 58). However, Ritchart et al. fails to disclose regulating the vacuum applied to the tissue, nor does Ritchart et al. disclose regulating the position of the blade to control the amount of tissue severed during blade movement. Zimmon et al. teaches that the size of a biopsy sample can be changed based on the amount of vacuum or suction, and the area of the opening that receives the sample (Col. 4, lines 20 – 28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Ritchart et al. to include the steps of regulating the

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vacuum applied to the tissue and regulating the position of the blade to allow for more or less area to be open to the tissue in order to modify the size of the biopsy sample as taught by Zimmon et al.

9. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,017,316 to Ritchart et al. in view of U.S. Patent No. 6,120,462 to Hibner et al.

In reference to claims 4 and 6, the amount of tissue severed is related to the movement of the blade as disclosed by Ritchart et al. However, Ritchart et al. fails to disclose regulating the speed of movement of the blade. Hibner et al. teaches a biopsy device wherein the speed the cutter is regulated (Col. 4, lines 47 – 56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to regulate the speed of the blade as disclosed by Ritchart et al. in order to maintain the speed of the blade in an optimal range while translating through tissue (Col. 2, lines 51 – 53).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,017,316 to Ritchart et al. in view of U.S. Patent No. 5,685,320 to Zimmon et al. as applied to claim 2 above and further in view of U.S. Patent No. 6,120,462 to Hibner et al.

In reference to claim 5, the amount of tissue severed is related to the movement of the blade as disclosed by Ritchart et al. However, Ritchart et al. fails to disclose regulating the speed of movement of the blade. Hibner et al. teaches a biopsy device wherein the speed the cutter is regulated (Col. 4, lines 47 – 56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to regulate the speed of the blade as disclosed by Ritchart et al. in order to maintain the speed of the blade in an optimal range while translating through tissue (Col. 2, lines 51 – 53).

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Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Application No. 2002/0082519 to Miller et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF
June 16, 2003



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700